UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/316,624	05/21/1999	SHALOM Z. HIRSCHMAN	4493-19CIP	8051

7590 02/26/2003

MYRON COHEN ESQ
COHEN PONTANI LIEBERMAN & PAVANE
551 FIFTH AVENUE
SUITE 1210
NEW YORK, NY 10176

EXAMINER	
CLOW, LORI A	
ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 02/26/2003

15

Please find below and/or attached an Office communication concerning this application or proceeding.

UNITED STATES PATENT AND TRADEMARK OFFICE

COMMISSIONER FOR PATENTS
UNITED STATES PATENT AND TRADEMARK OFFICE
WASHINGTON, D.C. 20231
www.uspto.gov

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Paper No. 15

Application Number: 09/316,624
Filing Date: May 21, 1999
Appellant(s): HIRSCHMAN, SHALOM Z.

Yunling Ren
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 23 July 2002.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

No amendment after final has been filed.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is correct.

(7) Grouping of Claims

The rejection of claims 1-4 stand or fall together because appellant's brief does not include a statement that this grouping of claims does not stand or fall together and reasons in support thereof. See 37 CFR 1.192(c)(7).

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

5,849,196	Kochel	12-1998

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

This appeal relates to a method of ameliorating a symptom of rheumatoid arthritis in a patient, comprising parenterally administering to said patient an effective symptom ameliorating amount of Product R in a range from about 2.5 microliters to about 40 microliters or 1 milliliter per kilogram of body weight per day in a pharmaceutically acceptable carrier.

The following ground(s) of rejection are applicable to the appealed claims:

(A) Claims 1-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The metes and bounds of the phrase "effective symptom ameliorating amount" in claims 1 and 4 are unclear. While the claims set forth the volume to be administered, there is no correlation between the volume to be administered and the active units or concentrations present in that volume of the formulation, such that one of ordinary skill in the art would be apprised of the scope of the invention. The specification provides two methods for making the Product R (page 10, lines 5-21; page 11 lines 1-21; and page 12, lines 1-7) but it is unclear that the two resulting products have the same level of activity. There have neither been examples of tests that have been run to establish any type of activity or relative activity associated with Product R, nor has there been evidence of activity been provided by applicant. The specification fails to establish both a standard activity of Product R preparation and an indication of how standard activities of Product R are to be determined. There is no titration of the active Product R formulations, such that one of skill in the art would be able to estimate proper dosages of liquid to be given. This is true, especially in light of the wide range of volumes to be administered. 2.5

microliters (2.5×10^{-6} liters), as suggested as a dosage at page 12, lines 13-17 is miniscule in comparison to 1 milliliter (1×10^{-3} liters), as suggested as a dosage at page 15, lines 4-5.

(B) Claims 1-4 are rejected under 35 U.S.C. 102(e) as being anticipated by Kochel (US 5,849,196).

The claims are drawn to methods of treating symptoms of rheumatoid arthritis by the administration of Product R. The specification describes two methods of making Product R (pages 12-14). Product R is a filtered form of a product Reticulose©, made from casein, beef peptone, RNA, serum, Sodium hydroxide or Hydrochloric acid and distilled water. The mixture is passed through at least a 0.45 micron filter, then a 0.2 micron filter. No chemical or biochemical analysis of the final composition is set forth in the specification.

Kochel (US 5,849,196 filed 7 October 1996) discloses a composition which is derived from the filtration of Reticulose©, which can be used to treat autoimmune disorders, such as rheumatoid arthritis (column 3, lines 1-7). Kochel discloses a composition containing a filtered form of Reticulose© comprising casein, beef peptone, RNA, serum, and sodium hydroxide (column 5, table at lines 12-20) and discloses the final proportions of the components. The composition is further passed through a milipore filter of 0.45 microns, and the product disclosed, made up of the lower molecular weight peptides (<8-15 kDa) is asserted to be useful in treating rheumatoid arthritis treatment.

The claims recite Product R, which appears to be made by two specific processes in the specification (pages 10-12). The MPEP discusses product-by-process claims in Chapter 2100: "Even though product-by-process claims are limited by and defined by the process,

determination of patentability is based upon the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as, or obvious from a product in the prior art, the claim is unpatentable even thought the prior product was made by a different process." See MPEP 2113.

Kochel sets forth products derived from the known product Reticulose© and methods of using that product, as claimed. The methods Kochel used to produce the composition, as well as the methods of treating rheumatoid arthritis, are very similar to those of the claimed invention. Whether the products resulting from the process are the same, is not clear, and the Office does not have the facilities to perform such comprehensive analyses. In a discussion of product-by-process claims, the court has said: "[W]hen the prior art discloses a product which reasonably appears either identical with or only slightly different that a product claimed in a product-by-process claim, a rejection based alternatively on either section 102 or section 103 of the statute is eminently fair and acceptable. As a practical matter, the Patent Office is not equipped to manufacture products by the myriad of processes put forth and then obtain prior art products so as to make physical comparisons therewith." *In re Brown*, 59 CCPA 1036, 1041, 459 F.2d 531, 535, 173 USPQ 685, 688 (1972). The court further addressed the issue of product-by-process claims in *In re Best*: "the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. Whether the rejection is based on 'inherency' under 35 USC 102, on 'prima facie obviousness' under 35 USC 103, jointly or alternatively, the burden of proof is the same [footnote omitted]." *In re Best*, 562 F.2d 1252, 1255, 195, USPQ 430, 433-434 (CCPA 1977).

(11) Response to Argument

(A) Applicant argues that the claim language "an effective symptom ameliorating amount of Product R in a range from about 2.5 microliters to about 40 microliters per kilogram of body weight per day" is clear and definite.

The fact, however, remains that the metes and bounds of the phrase are unclear for reasons set forth regarding concentration and volume. There lacks basis in the specification for the concentrations that make up the raw materials used in the manufacture of Product R. No indication as to molarity is evident. As is known by one of skill in the art, in order to calculate concentrations, it is necessary to have molarity of the solute in order to determine the final concentration of the solution. It is not known whether one microliter of the art composition is any different from one microliter of the invention. Absent any evidence that the concentrations of the starting materials of the instant application and the starting materials disclosed by Kochel are the same, it is completely conceivable that different starting amounts would yield the same product. There is no way to determine the difference, if any, between the composition of Kochel and the instant composition. Therefore, the claims still include Kochel in their scope. Furthermore, no correlation between the volume to be administered and the active units or concentrations present in that volume of the formulation has been established or provided, such that one of ordinary skill in the art would be apprised of the scope of the invention.

(B) Applicant asserts the Kochel (US 5,849,196) is directed to an improvement of a conventional pharmaceutical composition also containing peptides and nucleic acids and the

method of making such a composition. Furthermore, the composition resulting from the improvement ("improved composition") described by Kochel is entirely different from "Product R". Applicant goes on to compare the starting material of Product R verses the starting materials of Kochel, stating that the starting quantities differ and that it is "inconceivable that different initial materials would result in the same composition."

However, there lacks basis in the specification for the concentrations that make up the raw materials used in the manufacture of Product R. No indication as to molarity is evident. As is known by one of skill in the art, in order to calculate concentrations, it is necessary to have molarity of the solute in order to determine the final concentration of the solution. Absent any evidence that the concentrations of the starting materials of the instant application and the starting materials disclosed by Kochel are the same, it is completely conceivable that different starting amounts would yield the same product.

Applicant also asserts that different cooling temperatures result in different amounts of precipitation. However, absent knowledge of actual concentrations, there is no way to say that there is a difference in the two products. The same holds true for pH adjustments. In fact, the compositions appear to be the same. It is not known whether one microliter of the art composition is any different from one microliter of the invention.

Applicant further asserts that the process of Kochel yields a composition that inhibits phagocytosis and exhibits a molecular range of 1-25 kDa and a UV absorption profile as shown in Figure 5 ($A_{260/280} = 2.839$). Product R is described as having no inhibitory effect on phagocytosis and exhibiting a molecular weight range up to 14 kDa and a UV absorption profile as shown in Figure 1 of US Patent 6,303,153 ($A_{260/280}=1.998$).

However, it remains that applicant is presenting limitations that are not present in the pending claims. The pending claims fail to recite particular physical properties of Product R which are different from that of the composition disclosed in Kochel. The instant specification does not provide UV absorption profiles, nor does it provide information pertaining to the inhibition or lack of inhibition of phagocytosis.

(C) Applicant claims that anticipation under 35 USC 102(e) requires that "each and every" element as set forth in the claim as found expressly or inherently be described in the prior art reference. As such, applicant claims that claim 1 of the present invention and the teachings of Kochel are not the same. It is pointed out that the only limitation in the claims is the named Product R. However, no particular properties are clearly associated with that name or are present in the claims.

Applicant first asserts that Kochel fails to show that his composition is used to treat rheumatoid arthritis because Kochel only states that the low molecular weight portion of the composition is useful for treatment. However, no where in the instant specification is there mention of the molecular weight of Product R, nor is it clear as to what portion of the filtered product is utilized in treatment. Therefore, the claims of the instant invention still include the compositions of Kochel.

Applicant argues that Kochel fails to teach the administration route of the drug. However, the examples in Kochel, as in column 14, lines 39-50, clearly indicate that the composition is injected. Further, at column 13, lines 3-5, parenteral is defined.

Lastly, applicant argues that the "range of 2.5 to about 40 microliters" is not taught by Kochel. As described above, however, absent knowledge as to concentrations, there is no evidence to support that the injection amounts of Kochel differ from the instant invention.

Conclusions:

For reasons stated above, the composition and method of ameliorating rheumatoid arthritis as described in instant application are clearly anticipated by Kochel.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Lori A. Clow, Ph.D.
October 21, 2002

MICHAEL P. WOODWARD
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Conferees

MYRON COHEN ESQ
COHEN PONTANI LIEBERMAN & PAVANE
551 FIFTH AVENUE
SUITE 1210
NEW YORK, NY 10176

W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600